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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,636	10/28/2003	Mark A. Tapsak	DEXCOM.028A	5384
20995	7590	12/06/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			MOORE, MARGARET G	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1712	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/695,636

**Applicant(s)**

TAPSAK ET AL.

**Examiner**

Margaret G. Moore

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 to 134 is/are pending in the application.
- 4a) Of the above claim(s) 27 to 134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 to 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 to 26, drawn to a membrane, classified in class 428, subclass 447.
  - II. Claims 27 to 64, 69 to 72 and 77 to 102, drawn to a polymeric material, classified in class 528, subclass 32.
  - III. Claims 65 to 68, 73 to 76, drawn to process, classified in class 528, subclass 14.
  - IV. Claims 103 to 134, drawn to a method, classified in class 427, subclass 387.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and Group IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as a process that does not require a diluent or a process in which the polymeric material is other than that necessary in claim 103 or a process in which the silicone material is admixed or reacted with a non-silicone material.

3. Inventions of Group II and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as one in which an SiH siloxane having terminal telechelic groups is reacted with an unsaturated hydrophile, or one in which silanes or linear siloxanes are reacted to form the polymeric material rather than cyclic siloxanes.

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4. Inventions of Group I and Group II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the specific polymeric material found in claim 27. The subcombination has separate utility such as a precursor in making a silicone rubber or a cosmetic composition.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Rose Thiessen on 11/29/05 a provisional election was made without traverse to prosecute the invention of Group I, claims 1 to 26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27 to 134 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The information disclosure statements (IDS) submitted on 5/4/05 and 11/28/05 have been considered by the Examiner. For the record, the Examiner draws applicants' attention to MPEP 2004, paragraph 13, which addresses that long lists of documents should be avoided. Clearly the submission of 485 documents is considered to be long.

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Applicants could aid the Examiner in the examination process by noting the documents that are known to be of most significance, particularly as directed to the elected invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Initially, the Examiner would like to summarize the instant claims. While various claims require a domain having a particular property, such as a cell disruptive domain or a cell impermeable domain, these domains are subsequently defined by the silicone composition as found in claim 1. Thus while the prior art may not specifically teach each domain property, the prior art domains detailed below will inherently meet the property requirements of the claimed domain due to the fact that the silicone compositions therein meet that in claim 1. Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

11. Claims 1 to 12 and 17 to 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Kennedy.

Kennedy et al. teaches a multi-component polymeric network. See for instance the abstract, which teaches that the membrane contains, preferably, at least 3 domains including a silicone domain and a hydrophilic domain. These domains are reacted by

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means of a hydrosilation reaction, whereby the hydrophile is covalently attached to the silicone. See for instance column 3 and column 4, line 60 through column 5. The membranes are biocompatible and hemocompatible (column 3, line 6) and are permeable to water, hydrocarbons and oxygen (abstract), meeting the "controls transport of an analyte" requirement in claim 1. Column 16, line 33, teaches an implantable device. Various working examples, such as those shown on Table I, meet the claimed hydrophile content of claims 6, 9, 12, 20 and 23.

12. Claims 1 to 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Antwerp '060.

Van Antwerp teaches silicone containing biocompatible membranes that contain the reaction product of a hydrophilic polymer, a diisocyanate and a siloxane polymer. As such the hydrophile is covalently incorporated into the silicone composition. This contains at least three separate domains. Column 7, line 23, specifically discloses as a lower limit 10% by weight of a hydrophile, meeting the requirements of claims 6, 9, 12, 16, 20 and 23. This membrane is used as a glucose sensor, thus meeting the requirement of immobilized glucose oxidase. See column 9, lines 23 and 24. In addition, for claim 18, note that ionic components naturally found in the environment in which the sensor is placed will inherently be found in the silicone hydrophile domain since the domain in the claim is the same as that found in the prior art.

13. Claims 1 to 5, 7, 8, 10, 11, 17 to 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Al-Lamee.

Al-Lamee teaches biocompatible medical articles containing a membrane which is surface coated with a silicone composition in which a hydrophilic moiety is covalently attached. This comprises two domains. See for instance paragraph 15 and paragraph 17. Also note paragraph 10 which details an ionic component, meeting claim 18.

14. Claims 1 to 12, 17 and 19 to 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Keogh et al.

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Keogh et al. teach hydrophilic lenses and biomedical devices prepared from a siloxane having hydrophilic side chains. See for instance the structure shown on the top of columns 33 and 34 having at least two different domains. These membranes have good oxygen permeability. See columns 37 and 38. Preparation Examples IV and V result in a membrane having less than 5 wt% hydrophilic groups, meeting claims 6, 9, 12, 20 and 23.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Lamee.

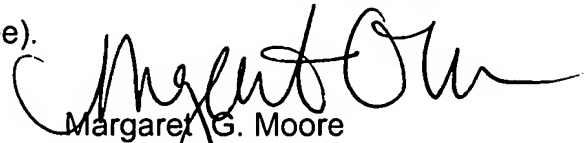
Al-Lamee teaches that the article therein can be used in glucose monitoring systems (paragraph 18). Thus while not specifically stating that the membrane contains immobilized glucose oxidase (see for instance paragraph 2 of applicants' specification). Thus the skilled artisan would have found the addition of glucose oxidase in the composition of Al-Lamee, when used in a glucose monitoring system, to have been obvious.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Margaret G. Moore whose telephone number is 571-272-1090. The examiner can normally be reached on Monday to Wednesday and Friday, 10am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Margaret G. Moore  
Primary Examiner  
Art Unit 1712

mgm  
12/1/05